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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,312	04/01/2004	Stephen S. Palmer	05558.0011.NPUS04	1876

7590 11/04/2005

Attention: IP Prosecution  
HOWREY SIMON ARNOLD & WHITE, LLP  
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Washington, DC 20004-2402

EXAMINER

DESAI, ANAND U

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 11/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/817,312

Applicant(s)

PALMER ET AL.

Examiner

Anand U. Desai, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-32,34-48 and 50-72 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-32,34-48 and 50-72 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. This office action is in response to Amendment filed on August 2, 2005. Claims 1-32, 34-48, and 50-72 are currently pending and are under examination.

#### Withdrawal of Rejections

2. The rejection of claims 10, 11, and 35 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn based on Applicants amendment.

#### Maintenance of Rejections

##### *Double Patenting*

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-7, 14-32, 34, 35, 37-39, 41-47, 50, 51, 54-56, 63, 64, 67, and 69 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of copending Application No. 10/498,639. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application are drawn to a method of follicular development and ovulation induction in a female host comprising the administration of an agent which increases follicle stimulating hormone concentration and administering a non-polypeptide cAMP level

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modulator that includes an inhibitor of a phosphodiesterase 4 isoform. The current claims are drawn to a method of stimulating ovarian follicular growth in a female comprising administering a medicament comprising a phosphodiesterase 4 inhibitor, and follicle stimulating hormone, or an agent having follicle stimulating hormone activity. Therefore, the compositions/medicament is structurally the same and would be expected to produce the same functional effect.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 1, 2, 3, 32, 34, and 35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2, 3, and 28 of copending Application No. 10/014,812. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application are drawn to a method of inducing ovulation in a female host comprising administering an inhibitor of phosphodiesterase type 4. The current application claims are drawn to a method of stimulating ovarian follicular growth or follicle maturation in a female comprising administering a medicament comprising a phosphodiesterase 4 inhibitor. Therefore, the compositions/medicament is structurally the same and would be expected to produce the same functional effect.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

*Claim Rejections - 35 USC § 102*

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
7. Claims 1-7, 14-32, 34, 35, 37-42, 44-47, 50, 51, 54, 55-58, 62, and 63 stand rejected under 35 U.S.C. 102(e) as being anticipated by Palmer, S. et al. (U.S. Patent Publication US2002/0065324 A1; 102(e) date is August 11, 2000).
8. The teaching of Palmer, S. et al. is disclosed in the Office Action mailed May 6, 2005.

*Response to Arguments*

9. Applicant states the cited reference fails to provide every element of the rejected claims. Applicant contends that Palmer et al. does not describe a method for stimulating ovarian follicular growth or follicle maturation. Applicant's arguments filed August 2, 2005 have been fully considered but they are not persuasive. Palmer et al. does disclose 'the stimulation of **follicular development** by administering an agent which increases the FSH concentrations during the follicular phase...The objective of the invention in increasing FSH relates solely to follicular development and maturation and not ovulation induction' (see paragraph [0013], 1<sup>st</sup> and 2<sup>nd</sup> sentences). Furthermore, claims 7-21 do claim a method of a combined treatment for stimulating follicular development and ovulation induction in a female comprising administering a non-polypeptide cAMP level modulator to said host prior to the luteal phase of the host's ovulatory cycle, wherein the non-polypeptide cAMP level modulator is a phosphodiesterase inhibitor (see particularly claims 7, and 13).

***Claim Rejections - 35 USC § 103***

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

11. Claims 1-11, 14-32, 34, 35, 37-47, 50-59, and 62-65 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Palmer, S. et al. (U.S. Patent Publication US2002/0065324 A1; 102(e) date is August 11, 2000) in view of Bowman, W.C et al. (Textbook of Pharmacology, 2<sup>nd</sup> edition pages 20.20-20.21 (1980)).

12. Claims 66-72 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Palmer, S. et al. (U.S. Patent Publication US2002/0065324 A1; 102(e) date is August 11, 2000) as applied to claims 1-11, 14-32, 34, 35, 37-47, 50-59, and 62-65 above, and further in view of Barbieri, R. et al. (Endocrine Reviews 20(3): 249-252 (1999)).

***Response to Arguments***

Applicant states the cited reference, Palmer et al., fails to provide every element of the rejected claims, and that neither Bowman et al. nor Barbieri et al. cures the failure of Palmer et al. Applicant contends that Palmer et al. does not describe a method for stimulating ovarian follicular growth or follicle maturation. Applicant's arguments filed August 2, 2005 have been fully considered but they are not persuasive. The response to the Palmer et al. reference is discussed above.

In addition, Bowman et al. does describe the temporal pattern and concentration of hormonal changes associated with the menstrual cycle, and Barbieri et al. does disclose suppression of pituitary gonadotropin secretion with a GnRH analogue that permits longer ovarian stimulation, which results in the development of a greater number of large mature

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follicles. Therefore, it would have been obvious to the person having ordinary skill in the art to administer the PDE inhibitor as disclosed by Palmer, S. et al. and the cycling hormones at the time and concentration being described by Bowman, W.C. to stimulate ovarian follicle growth and maturation in a female (current application, claims 1-11, 14-32, 34, 35, 37-47, 50-59, and 62-65) and it would have been obvious to the person having ordinary skill in the art to administer the GnRH analogue as described by Barbieri, R. et al. prior to the administration of the PDE inhibitor and the FSH hormone as disclosed by Palmer, S. et al. to stimulate ovarian follicle growth, and thus retrieve a greater number of competent oocytes to harvest and use in in-vitro fertilization for a female (current application, claims 66-72).

### *Conclusion*

13. No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

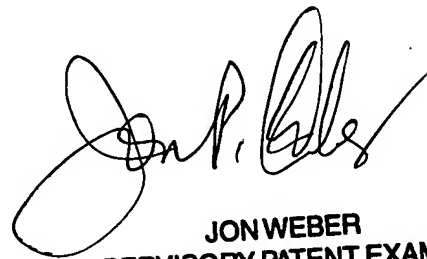
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 7:00 a.m. - 3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

October 27, 2005



**JON WEBER**  
**SUPERVISORY PATENT EXAMINER**